PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Roger P. Jackson

Serial No.: 10/784,066 Date: January 19, 2010

Filed: February 20, 2004 Group Art Unit: 3732

Exam: David C. Comstock

For: CLOSURE FOR ROD RECEIVING ORTHOPEDIC IMPLANT HAVING LEFT HANDED THREAD REMOVAL

- -

Kansas City, Missouri

Appeal No._____

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed in support of the Notice of Appeal in this application which was mailed on December 1, 2008.

The fees required under 41.2(b)(2) are submitted herewith.

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TABLE OF CONTENTS

I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

The following is a related patent application on appeal to the Board of Appeals:

Serial No. 10/783,889 for which an appeal brief is being concurrently filed and with respect to which no decision has been entered.

III STATUS OF CLAIMS

Claims canceled:	none
Claims pending:	1 to 20
Claims rejected:	1 to 20
Claims allowed:	none
Claims being appealed:	1 to 20

IIIa JURISDICTIONAL STATEMENT

This appeal is an appeal from a Patent Office action under 35 U.S.C. 134(a).

The Office action appealed from was mailed December 1, 2008. Several actions during the pendency of this application have been "Final."

The Notice of Appeal was filed December 1, 2008.

The Appeal Brief was filed May 1, 2009 with a Request for Extension of Time until May 1, 2009 to file the Brief and is being refiled on January 19, 2010 in accordance with the Office action mailed September 16, 2009 with an Extension of Time.

IV STATUS OF AMENDMENTS

There are no outstanding or pending amendments.

V SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 1 is directed to a closure {1, page 28, line 4 to page 33, line 21, and see Figs. 1-9} for setting engagement with a structural member {8, page 28, line 8 to page 33, line 21, and see Figs. 1-9} and comprising a substantially cylindrical body {4, page 28, lines 6-7, and page 29, lines 1-2} having an outer cylindrical surface relative to a central closure axis {25,page 29, lines 1-2}; a guide and advancement flange {35, page 30, line 4 to page 31, line 8, and see Figs. 1-2} extending helically

about said outer cylindrical surface and having a forward advancement direction relative to the closure axis {see Figs. 1-2}, said flange having a leading surface {27, page 29, lines 1-4, and see Fig. 2} and a trailing surface {28, page 29, lines 1-4, and see Figs. 1-2} relative to said forward advancement direction; at least one of the leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component {37, page 30, lines 6-19} facing generally toward the closure axis; a driving structure {6, page 28, lines 6-8, and page 29, line 4 to page 30, line 3} for rotating and torquing the body to a preselected torque; and said body having an axially aligned bore {2, page 28, lines 5-6, and page 32, lines 18-21, and see Figs. 3, 5, 8 and 9} opening on a trailing surface of the body {page 32, line 21 to page 33, line 2, see especially Figs. 8-9}; the bore having a left handed thread {47, page 32, lines 19-21} that includes a plurality of complete revolutions of the thread about the bore {see Figs. 5 and 9} therein that is sized and shaped to be adapted to receive a removal tool {50, page 33, lines 3-14} with a mating left handed thread {55, page 33, lines 5-7} for removing said body subsequent to installation {page 33, lines 13-14}.

Claim 9 is directed to a closure {1, page 28, line 4 to page 33, line 21, and see Figs. 1-9} for setting engagement with a structural member {8, page 28, line 8 to page 33, line 21, and see Figs. 1-9} and comprising a body {4, page 28, lines 6-7, and page 29, lines 1-2} having an outer cylindrical surface relative to a central closure axis {25, page 29, lines 1-2} and a driving installation head {6, page 28, lines 6-7}; a guide and advancement flange {35, page 30, line 4 to page 31, line 8, and see Figs. 1-2} extending helically and substantially continuously about the outer cylindrical surface and having a forward advancement direction relative to the closure axis {see Figs. 1-2}, the flange having a trailing surface {28, page 29, lines 1-4, and see Figs. 1-2} relative to the forward advancement direction; the trailing surface being compound in contour and including an inward anti-splay surface component {37, page 30, lines 6-19} facing generally toward the closure axis; and the body having an axially aligned bore {2, page 28, lines 6-8, and page 29, line 4 to page 30, line 3} formed therein that opens onto a trailing surface of the body {page 32, line 21 to page 33, line 2, see especially Figs. 8-9}; the bore having a helically wound left handed thread {47, page 32, lines 19-21} therein that extends a

plurality of revolutions about the bore {see Figs. 5 and 9}; the bore thread being sized and shaped to receive a removal tool {50, page 33, lines 3-14} having a mating left handed thread {55, page 33, lines 5-7}.

Claim 15 is directed to a closure {1, page 28, line 4 to page 33, line 21, and see Figs. 1-9} for setting engagement with a structural member {8, page 28, line 8 to page 33, line 21, and see Figs. 1-9} and including a substantially cylindrical body {4, page 28, lines 6-7, and page 29, lines 1-2} having an outer cylindrical surface relative to a central closure axis {25, page 29, lines 1-2} and a substantially continuous guide and advancement flange {35, page 30, line 4 to page 31, line 8, and see Figs. 1-2} extending helically about the outer cylindrical surface and having a forward advancement direction relative to the screw axis {see Figs. 1-2}; said flange having a leading surface {27, page 29, lines 1-4, and see Fig. 2} and a trailing surface {28, page 29, lines 1-4, and see Figs. 1-2} relative to the forward advancement direction; at least one of the leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component {37, page 30,

lines 6-19} facing generally toward the closure axis; and said body having an axially aligned bore {2, page 28, lines 5-6, and page 32, lines 18-21, and see Figs. 3, 5, 8 and 9} that opens onto a trailing surface of said body {page 32, line 21 to page 33, line 2, see especially Figs. 8-9}; the bore having a left handed helically wound thread {47, page 32, lines 19-21} that extends a plurality of revolutions around the bore {see Figs. 5 and 9} sized and shaped to mate with a removal tool {50, page 33, lines 3-14} having a mating left handed thread.

VI GROUNDS OF REJECTION TO BE REVIEWED

1) Are Claims 1 to 20 properly rejected under 35 U.S.C. 103(a) as being unpatentable over Shafer (DE 298 10 789 U1) in view of Jackson (6,004,349)?

VII ARGUMENT

BACKGROUND SUPPORT FOR ARGUMENT

Applicant is an orthopedic surgeon specializing in spinal surgery. He works daily with implanting spinal implants of the type found in the present application. He has also worked

extensively with manufacturing companies that produce spinal implants both in designing entire product lines and individual implants.

Prior to the filing of the filing of the present application, Dr. Jackson recognized that there was an inherent problem with open headed bone screws of the type used in spinal surgeries. In particular, such bone screws have a receiver or head with a pair of spaced upstanding arms that form a rod receiving channel between them. The implants are quite small with a receiver that is only slightly bigger than a pencil eraser. Perhaps the most significant problem with such open headed bone screws is that the arms are relatively small and cannot withstand much outward directed force, otherwise the arms will splay or spread which can lead to catastrophic failure of the implant, because an associated closure and rod become loose in the receiver after which the rod moves relative to the receiver.

One type of closure is illustrated in the Puno Patent No. 5,474,555 and provides an outer nut that goes entirely around the arms that holds the arms to keep them from splaying. However, there are several problems with the Puno nut. In particular,

there is little space within which to work around the receiver along the rod. Such space is often referred to as the "run on the rod". The Puno nut significantly increases the space taken up by the bone screw along the run on the rod making it unusable in some situations. Furthermore, the nut is large and heavy. Both of these factors make the outer nut undesirable.

Other inventors, including applicant, have developed closures that slide sideways into slots in the receiver. These do not require rotation; however, such closures are hard to use in minimally invasive surgery and require a second structure, such as a set screw, for locking the rod relative to the receiver.

Other inventors have tried to use a threaded plug for the closure that uses a conventional V-thread and is threadably received between the arms. The problem with a V-thread type plug where the sides of the thread are, for example, at a 45° angle with respect to the base is that the torque needed to tighten the closure against the rod to lock the rod in place produces splaying of the arms. This is because the surfaces of such a thread cause approximately half of the downward force to be exerted axially and half radially outward. Because the closures

must be set with a high torque for such a small device (normally about 100 inch pounds), the outward force can push the walls so as to splay them.

An inventor by the name of Metz-Stavenhagen suggested using buttress threads where, in theory, all of the forces should be exerted axially. Applicant and others, have also shown in patent applications and used helically wound reverse angle threads on the closure. Reverse angle threads should, in theory, actually pull the arms radially inward toward the closure. While buttress and reverse angle V-threads perform better than threads where the sides are both at acute angles relative to the base, all V-threads still have an inherent problem. In particular, so much force is applied in torquing the closure and the threads are so thin that the threads can bend. As the threads are essentially smooth on both sides, after bending, they can radially slide relative to each other under torquing which leads to splaying.

One further method has been developed to prevent splaying. This involves a closure with one or more flanges that extend radially outward and are received in similar shaped receivers in the arms. These distinguish from the closures noted above that slide in sideways in that they are rotated, twisted or screwed

approximately one fourth revolution to seat in the receiver. Applicant is of the opinion that the cited Schafer reference (German 298 10 798) also shows such a structure which will be discussed more extensively in the argument's section. There are a number of problems with such devices. In particular, such closures must be pushed down against the rod until the flanges on the closure align with the flange receivers on the arms and then rotated until the two parts join which typically requires a 90° rotation, twist or screwing of the closure. During assembly, the closure of such devices can not be advanced in a helically wound path under the guidance of the receiver, so such closures are difficult to install and typically another device such as a set screw received in an axially aligned bore or the like must be used to lock the rod.

Applicant has developed a helically wound closure with a radially interlocking structure between the closure and the arms of the receiver that resists splaying of the arms even at a high setting torque and that requires no other structure, such as a set screw, to lock the rod in place. The high torque ensures that the rod will not slip or move relative to the receiver which can seriously compromise the value of the implant and could

cripple the patient.

ARGUMENT WITH RESPECT TO REJECTION OF CLAIMS 1 TO 20 AS OBVIOUS IN VIEW OF A COMBINATION OF DE 298 10 798 AND 6,004,349

The pending claims were rejected as obvious in view of a combination of Schafer (German 298 10 798) and Jackson (6,004,349).

The cited Schafer patent is directed to two different embodiments. The first embodiment is a closure of the type with a reverse angle thread. The reverse angle thread of Fig. 1 is a V-thread with smooth sides which can bend and radially slide relative to a mating thread and is urged to not in any way show or describe the radially interlocking structures between the closure body and arms as is called for in applicant's claims. More importantly, the first embodiment is not shown or described as being helically wound. It is described as being screwed in; however, the term screw can mean simple rotation into something. It is believed that the first embodiment of Schafer is a push down and twist structure like the second embodiment and as discussed below. This interpretation is supported by the Schafer specification and is consistent with other devices that Schafer

patented and produced.

The second cited embodiment of Schafer is shown in Fig. 2. This embodiment was apparently added as a quick after thought, is poorly described, and includes only a partial cross section of the receiver in Fig. 2 and a single paragraph describing the embodiment of Fig. 2. The last Office Action cites the paragraph describing Fig. 2 as follows:

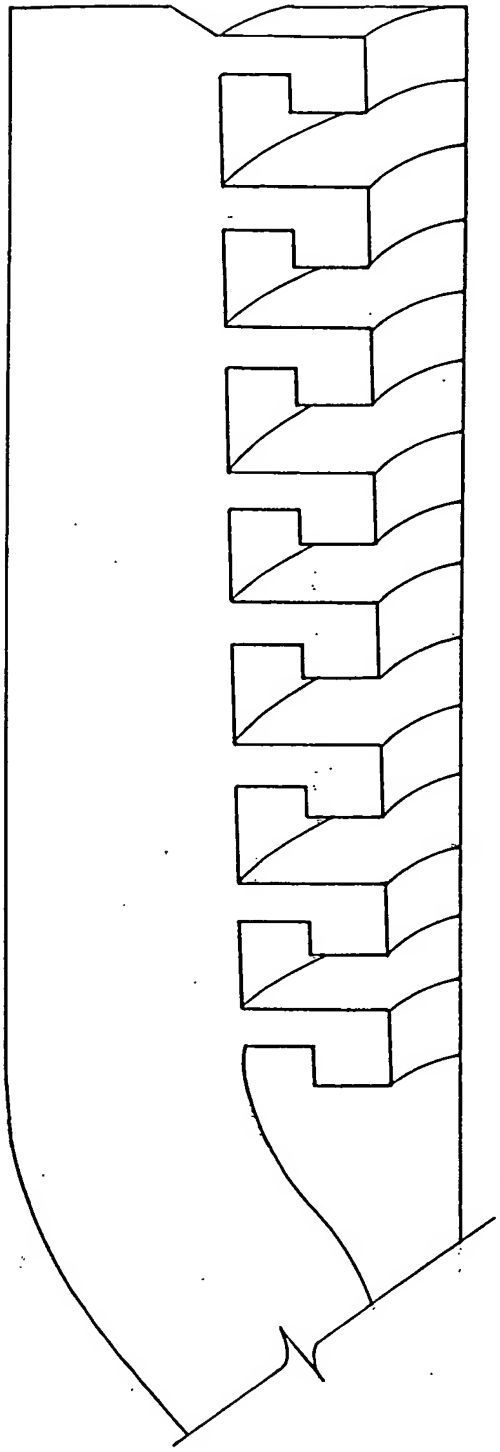
> "In the exemplary embodiment shown in Figure 2, the bifurcated head 4 of the bone screw 1 likewise has a **thread**, which, however, has a top flank 11 and a bottom flank 10 embodied in a stepped fashion. The shoulder of the bottom flank 10 is shaped such that it forms an undercut 17. This undercut 17, particularly by means of the shoulder 18, prevents the legs 5 from being bent radially outward while the **grub screw** 3 is being **screwed in**. A positive lock is thus produced in the radial direction between the bifurcated head 4 and grub screw 3. This positive lock prevents, as previously mentioned, any slippage of the leg 5." (Emphasis added by the Office action).

The Office action argues that this paragraph and Fig. 2

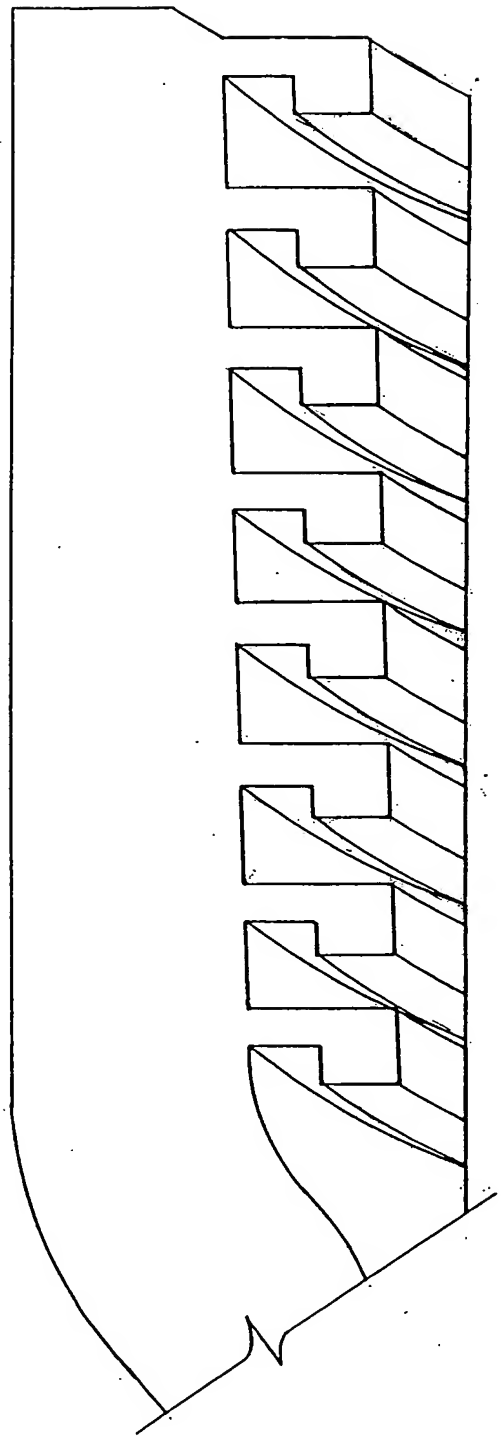
clearly show and describe a helically wound structure of the type claimed by applicant. Applicant respectfully disagrees.

In particular, the cited Schafer device does not show a helically wound pitch and further, one must take the disclosure of Schafer in light of what was known to one having ordinary skill in the art at the priority date of the present application. The art of this invention is quite complex, but no one had previously shown an interlocking structure that was helically wound. When reviewing the Schafer patent, as one having skill in the art at the priority date would have done, an engineer or other skilled person would look to see what Schafer actually teaches. The second embodiment of Schafer neither shows or teaches a closure, so a closure must be somehow imagined to work with the receiver of Fig. 2. In studying the disclosed Schafer receiver to see how to make a closure, it is clear that all of the tiers of structure (seven complete in total) are equally spaced from the bottom of the channel <u>on both the front and back sides of each tier</u>, as shown in the drawing. Consequently, it is impossible for the tiers to have a pitch and, likewise, it is impossible for such tiers to be helically wound. To be helically wound each tier must have such a pitch to go from one tier to the

next with each 360 degree revolution of the tier. Further, in Fig. 2 each tier would have to slope downward toward the rear and in Schafer Fig. 2 each tier is essentially horizontal. On the following page is a representation on the left that is Fig. 2 of the Schafer reference and a representation on the right that is of a structure modified with respect to Schafer, if Schafer were modified to be helically wound.



SCHAFER
FIG. 2



SCHAFER MODIFIED TO BE HELICALLY WOUND CONSISTENT WITH APPLICANT'S INVENTION

It is apparent from reviewing these two images that one having skill in the art would immediately see that the device of Fig. 2 of Schafer is not helically wound and that is was of the type of closure wherein the mating structure on the closure was not helically wound, but rather the closure and receiver were aligned by pushing down and then the closure was designed to be screwed in by twisting or rotating 90° to secure the parts together.

The geometry of applicant's device is quite complex because a compound and complicated surface is being helically wound about the closure and a like structure is being wound about the inside of the arms. It is urged that at the time of filing, it was not apparent to one having skill in the art that such a complex structure could be made or that it could work upon rotation during assembly. Perhaps even more important is that the Schafer structure does not suggest that one having ordinary skill in the art should even look at or try to make a helically wound device. It is noted that machine shops were unable to manufacture applicant's device for many years because of the great complexity, even after applicant told them what he wanted. The Office action points out that the short disclosure in Schafer indicates that there is a thread and that a grub screw is screwed

into it. A closure of the push and twist type, described above, is clearly not helically wound. In addition, it is noted that a structure that mates upon rotating 90° can be called a grub screw and rotation or twisting can be interpreted and translated from the German into English as being "screwed in" in the Schafer disclosure to distinguish from the closures that are slid in sideways without rotating. Consequently, it is believed that applicant's interpretation of Schafer is completely consistent with the written description, especially as it would be interpreted by one with skill in the art at the time. The drawing of Schafer would either teach one to make a non helically wound device or, alternatively, fails to teach how to make any effective device.

It is further noted that Schafer was a well known German inventor who had many U.S. patents. It is interesting to review these patents because of what his later patents show. Schafer's 289 10 798 German patent has publication and other dates in the late 1990's. Nevertheless, when he designed the later closures, he used the "push down to align and then twist 90°" structure that is urged to be shown in the earlier patent rather than a helical wound structure. For example, the following views are from his US 6,340,749 patent that was filed in 2002.

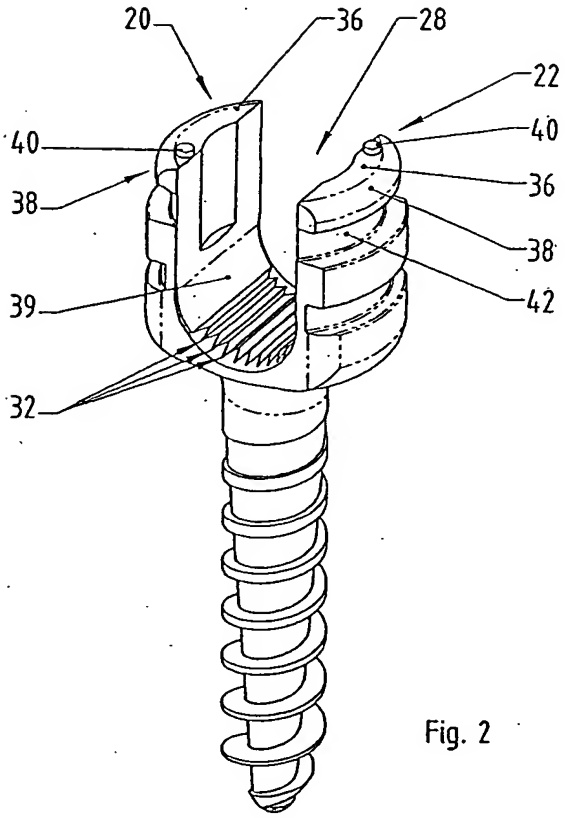


Fig. 2

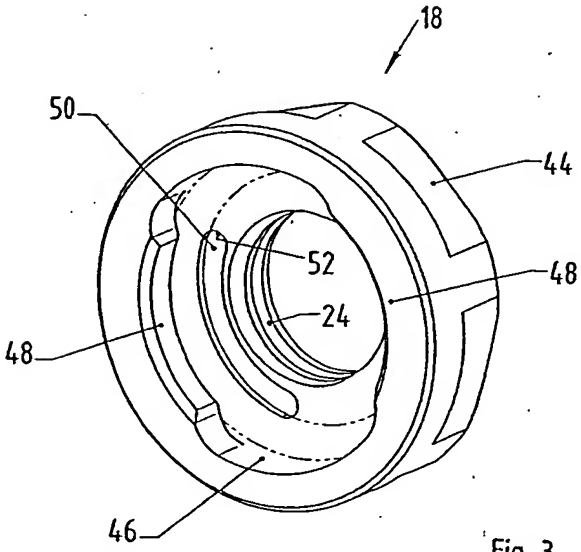


Fig. 3

The structure shown in the 6,540,749 patent clearly has an "push down and align and then twist 90°" closure (nut 18) that mates with a receiver (head 16) having receiving structure. If Schafer had conceived of the helically wound structure earlier,

why did he use the "align and twist" structure rather than the preferable helically wound structure that does not require an additional locking screw (26)? The answer is that Schafer had not envisioned such technology and that anyone of ordinary skill in the art who reviewed Schafer's patent, also would not envision such technology based upon his teachings. Persons trying to better understand the poorly presented Schafer reference that was cited may look to his later patents and see the "align and twist" type closure, as is found in Patent No. 6,540,749.

It is noted that applicant's prior patent 6,004,349 is cited as satisfying the claim requirement of a left handed thread having a plurality of complete revolutions. The earlier Jackson patent was directed to a set screw (not a closure) that had a conventional V-thread and that was designed for being received in a fully surrounding bore. The set screw was not heavily torqued and because of this could be removed with an easy out provided a starter thread of about one half revolution was provided. The thread was gripped by an easy out for removal and required a large downward force to be exerted by the physician which was both difficult to accomplish and dangerous to the patient. Applicant developed his current left handed thread removal system to replace the earlier problematic easy out structure.

Applicant's current invention is to a closure between arms that is heavily torqued to give a good solid seat. The removal structure for this closure is a left handed thread of multiple revolutions that mates with a similar removal tool. Because of the high setting torque, the simple partial revolution thread taught in applicant's prior patent is insufficient and multiple revolutions are required. It is urged that applicant's invention further distinguishes from the cited prior art for this reason, as the cited prior art fails to teach one of skill in the art to use the stronger multiple revolution thread with a different tool to allow for removal.

Consequently, it is urged that a combination of Schafer and Jackson fails to make obvious the pending claims for the noted reasons. It is especially noted that none of the cited art teaches or shows how to produce a closure with a helically wound and radially interlocking guide and advancement structure that allows firm seating of the closure when fully assembled or the combination of such a firm seating with the left handed threaded bore with a thread of multiple revolutions that allows removal under higher torque than can be provided by an easy out. The earlier Jackson device does not teach how to make the improved version to handle the greater torque. It is also urged that

Schafer fails to in anyway suggest or teach applicant's claimed invention to one having ordinary skill in the art whether taken alone or in combination with the cited Jackson reference.

VIII CLAIMS APPENDIX

A. APPEALED CLAIMS

Claim 1 A closure for setting engagement with a structural member and comprising:

(a) a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis;

(b) a guide and advancement flange extending helically about said outer cylindrical surface and having a forward advancement direction relative to said closure axis, said flange having a leading surface and a trailing surface relative to said forward advancement direction;

(c) at least one of said leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component facing generally toward said closure axis;

(d) a driving structure for rotating and torquing said body to a preselected torque; and

(e) said body having an axially aligned bore opening on a trailing surface of said body; said bore having a left handed thread that includes a plurality of complete revolutions of the thread about the bore therein that

is sized and shaped to be adapted to receive a removal tool with a mating left handed thread for removing said body subsequent to installation.

Claim 2 The closure as set forth in Claim 1 wherein said bore is exposed by removal of said driving structure.

Claim 3 The closure as set forth in Claim 1 wherein:

(a) said apertures extend from said body trailing surface partially therethrough.

Claim 4 The closure as set forth in Claim 1 wherein:

(a) said driving structure is an installation head that includes a grippable radially outer surface that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region formed in such a manner that said breakaway region fails in response to a selected level of torque between said installation head and said closure to enable separation of said installation head from said closure.

Claim 5 The closure as set forth in Claim 1 and including:

(a) said closure having a leading surface relative to said forward advancement direction; and

(b) said body having a V-shaped set ring and an axially aligned point formed on said leading end to enhance setting engagement of said closure into a surface of a structural member.

Claim 6 The closure as set forth in Claim 1 in combination with a bone implant screw adapted for connection to a bone fixation structural member, said bone implant screw including:

(a) a threaded shank adapted for threaded implanting into a bone;

(b) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel therebetween to receive a bone fixation structural member; and

(c) said mutually facing channel surfaces each having mating guide and advancement structure formed therein which are compatible for mating with said guide and advancement flange of said closure to enable rotation guiding and advancement of said closure into said

channel so as to be adapted to clamp said bone fixation structural member when positioned therein.

Claim 7 The closure and bone implant screw combination as set forth in Claim 6 wherein:

(a) said mating guide and advancement structure of said bone implant screw include an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said closure to provide an interlocking fit when joined so as to resist splaying of said arms in reaction to forces applied thereto.

Claim 8 The closure and bone screw combination as set forth in Claim 7 wherein:

(a) said guide and advancement flange has a relatively enlarged outer periphery which forms said inward anti-splay surface component;

(b) said mating guide and advancement structures are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw.

Claim 9 A closure for setting engagement with a structural member and comprising:

(a) a body having an outer cylindrical surface relative to a central closure axis and a driving installation head;

(b) a guide and advancement flange extending helically and substantially continuously about said outer cylindrical surface and having a forward advancement direction relative to said closure axis, said flange having a trailing surface relative to said forward advancement direction;

(c) said trailing surface being compound in contour and including an inward anti-splay surface component facing generally toward said closure axis; and

(d) said body having an axially aligned bore formed therein that opens onto a trailing surface of said body; said bore having a helically wound left handed thread therein that extends a plurality of revolutions about

the bore; said bore thread being sized and shaped to receive a removal tool having a mating left handed thread.

Claim 10 The closure as set forth in Claim 9 including:

(a) an installation head that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region formed in such a manner that said breakaway region fails in response to a selected level of torque between said installation head and said closure to enable separation of said installation head from said closure.

Claim 11 The closure as set forth in Claim 9 and including:

(a) said closure having a leading end relative to said forward advancement direction; and

(b) said closure having a V-shaped set ring and an axially aligned point formed on said leading end to enhance setting engagement of said closure into a surface of a structural member.

Claim 12 The closure as set forth in Claim 9 in combination with a bone implant screw adapted for connection to a bone fixation structural member, said bone implant screw including:

(a) a threaded shank adapted for threaded implanting into a bone;

(b) an open head having a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member therebetween; and

(c) each of said mutually facing channel surfaces having mating internal guide and advancement structure formed therein which are compatible with said flange of said closure to enable advancement of said closure into said channel to thereby clamp said bone fixation structural member when positioned therein.

Claim 13 The closure and bone implant screw combination as set forth in Claim 12 wherein:

(a) each of said guide and advancement structures of said bone implant screw include an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said closure in such a

manner as to resist a tendency of said arms to splay in reaction to torquing said closure into engagement with said fixation structural member.

Claim 14 The combination as set forth in Claim 13 wherein:

(a) said flange has a relatively enlarged outer periphery which forms said inward anti-splay surface component;

(b) each of said guide and advancement structures are contoured in a complementary manner to said external thread to form said outward anti-splay surface component; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is rotated into said open screw head of said bone implant screw.

Claim 15 A closure for setting engagement with a structural member and including a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis and a substantially continuous guide and advancement flange extending helically about said outer cylindrical surface and having a forward advancement direction relative to said screw axis; said

flange having a leading surface and a trailing surface relative to said forward advancement direction; at least one of said leading surface or said trailing surface being compound in contour and including an inward anti-splay surface component facing generally toward said closure axis; and said body having an axially aligned bore that opens onto a trailing surface of said body; said bore having a left handed helically wound thread that extends a plurality of revolutions around the bore sized and shaped to mate with a removal tool having a mating left handed thread.

Claim 16 The closure as set forth in Claim 15 wherein said bore extends from said trailing surface of said body only partially through said body.

Claim 17 The closure as set forth in Claim 15 and including:

(a) an installation head that is shaped to enable non-slip engagement of said installation head by an installation tool; and

(b) said installation head being connected to said closure by a breakaway region formed in such a manner that said breakaway region fails in response to a selected level

of torque between said installation head and said closure to enable separation of said installation head from said closure.

Claim 18 The closure as set forth in Claim 15 wherein:

(a) said closure has a leading end relative to said forward advancement direction; and

(b) said closure having a V-shaped set ring and a point formed on said forward end to enhance setting engagement of said closure into a surface of such a structural member.

Claim 19 The closure as set forth in Claim 15 in combination with a bone screw adapted for connection to a bone fixation structural member, said bone implant screw including:

(a) a threaded shank adapted for threaded implantation into a bone;

(b) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member;

(c) each of said mutually facing channel surfaces having

respective mating guide and advancement structures formed therein which are compatible with said guide and advancement flange of said closure to enable guiding and advancement of said closure into said channel to thereby clamp said bone fixation structural member therein; and

(d) said mating guide and advancement structures of said bone implant screw including an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said closure in such a manner as to resist a tendency of said arms to splay in reaction to forces being applied thereto.

Claim 20 The closure and bone screw combination as set forth in Claim 19 wherein:

(a) said guide and advancement flange has a relatively enlarged outer periphery region which forms said inward anti-splay surface component;

(b) said mating guide and advancement structures are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay

surface component; and

(c) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw.

IX EVIDENCE APPENDIX

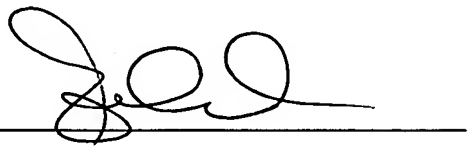
NONE

X RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

Roger P. Jackson

BY: 

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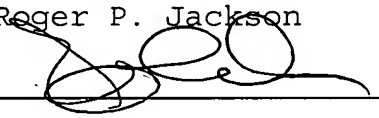
By 

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